

**Statement by Dr. Charles Finder**  
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**Food and Drug Administration**

Perry Beale inspected and maintained mammography equipment in approximately 53 facilities in the states of Maryland, North Carolina, Pennsylvania, Virginia, West Virginia and the District of Columbia.

The FDA evaluated the potential risks caused by Mr. Beale's criminal activities as they related to mammography, including the potential for excessive radiation dose and problems with image quality. Although Mr. Beale's actions were a flagrant disregard of federal mammography regulations, FDA believes that, based on current information, Mr. Beale's activities posed no health risk to mammography patients and therefore these patients do not need to take any action as a result.

Under the Mammography Quality Standards Act (MQSA), numerous checks and balances are built into the national mammography program to protect patients. For example, dose is independently measured by an inspector on a yearly basis and by the facility's accreditation body every three years. Similarly, image quality (through the use of a phantom) is evaluated by the inspector and accreditation body on the same schedule. This evaluation is performed using a phantom, which is a device containing objects that simulate structures found in the breast. Image quality is measured by seeing how many objects can be identified on the image. Equipment is also tested by the equipment installers and repair technicians who also perform routine preventative maintenance.

In addition to these safeguards, image quality is evaluated by the facility's radiological technologist as part of the daily, weekly, quarterly and semi-annual quality control testing. The radiological technologist and the interpreting physician also evaluate the clinical image quality of the films of every patient.

FDA's own investigation of the inspection records at the facilities where Mr. Beale serviced equipment did not demonstrate dose or significant phantom image quality problems.

Despite Mr. Beale's actions, FDA believes that based on all available information the safety systems built into the MQSA program worked, and because of that women who had mammograms at the involved facilities should not be concerned about the quality of their mammograms.